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QUIDEL

Solana®
GBS ASSAY

FOR USE WITH SOLANA
For the qualitative *in vitro* diagnostic detection of Group B Streptococcus in either LIM or Carrot enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation.

For *in vitro* diagnostic use.

℞ ONLY

A symbols glossary can be found at quidel.com/glossary.

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INTENDED USE

The Solana GBS assay is a qualitative *in vitro* diagnostic test for detection of Group B Streptococcus in either LIM or Carrot enrichment broth cultures of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation.

The Solana GBS Assay utilizes helicase-dependent amplification (HDA) of the Thiolase (atoB) gene sequence. The Solana GBS Assay is intended for use only with the Solana Instrument.

The Solana GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.

SUMMARY AND EXPLANATION

Streptococcus agalactiae (Group B *Streptococcus* or GBS) is a Gram-positive coccus bacterium that is found in a number of sources in healthy adults (gastrointestinal, genital and urinary tract). It is estimated that any given time 20% of pregnant women are colonized with GBS. It is associated with asymptomatic bacteria, urinary tract infection, and amnionitis, and in women who have recently delivered, it causes endometritis and wound infection.[1]

In the 1970's, GBS was a leading infectious cause of early neonatal morbidity and mortality.[2] As a result of prevention efforts, incidence of GBS has declined dramatically, from 1.7 cases per 1,000 live births in the early 1990s to 0.34 case per 1,000 live births in 2008. The CDC estimates that GBS has caused approximately 1,200 cases of early-onset invasive disease per year.[3] The most common clinical syndromes of early-onset disease are sepsis and pneumonia; less frequently, early-onset infections can lead to meningitis. Mortality of babies born at term (≥ 37 weeks' gestation) is 2 to 3%, but among preterm infants the mortality can be as high as 30%.

Screening for GBS colonization in antepartum women (between 35 and 37 weeks' gestation), is one of the key components of the CDC's GBS screening strategy and is an effective mechanism for prevention of perinatal Group B Streptococcal disease. As colonization may be transient, intermittent or persistent throughout pregnancy, screening is most effective when performed when specimens are collected no more than five weeks (35 to 37 weeks' gestation) prior to delivery and after enrichment with selective broth medium.

PRINCIPLE OF THE TEST

The Solana GBS Assay amplifies and detects GBS DNA in an enrichment broth cultures isolated of vaginal/rectal swabs from antepartum women following 18 to 24 hours of incubation.

The assay consists of two (2) major steps: 1) specimen preparation, and 2) amplification and detection of target sequence specific to GBS using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe.

Patient specimen is transferred to a Process Buffer tube, subjected to heat treatment at 95° ± 2°C for 5 minutes and mixed. The processed sample is transferred to a Reaction Tube and mixed. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the processed sample, the Reaction Tube is placed in Solana for amplification and detection of specific target sequences. In Solana, the GBS target sequence is amplified by GBS specific primers and detected by a GBS specific fluorescence probe included in the Reaction Tube. A competitive process control (PRC) is included in the Process Buffer tube to monitor sample processing, for the presence of inhibitory substances in clinical samples, reagent or device failure. The PRC target is amplified by specific primers and detected by a PRC specific fluorescence probe.

The target and PRC probes are labeled with a quencher on one end and a fluorophore (FAM or ROX, respectively) on the other end. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to GBS or PRC amplicons, the

fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana will then report the test results to the user on its display screen, and it can print out the results via the attached printer.

MATERIALS PROVIDED

Cat. # M311
48 Tests per Kit

Component	Quantity	Storage
Process Buffer	48 tubes/kit 1.0 mL	2°C to 8°C
Reaction Tubes	48 tubes/kit	2°C to 8°C

MATERIALS REQUIRED BUT NOT PROVIDED

- External controls for GBS (e.g. Quidel Molecular GBS Control Set, Cat. #M116, which contains positive and negative controls, serves as an external processing and extraction control)
- Sterile DNase-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Vortex Mixer
- Scissors or a blade
- Workflow Tray
- Transfer Rack
- Heat block capable of 95° ± 2°C temperature
- Solana instrument
- Enrichment broth culture (e.g. LIM, Carrot)

WARNINGS AND PRECAUTIONS

- Refer to the Solana User Manual for further information regarding instrument installation and operation.
- All reagents are for *in vitro* diagnostic use only.
- Only use the protocol described in this package insert. Deviations from the protocol may give erroneous results.
- Treat all specimen/samples as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
- All tubes should be capped tightly prior to vortexing.
- Proper sample collection, storage and transport are essential for correct results.
- Store assay reagents as indicated on their individual labels.
- Reagents are not interchangeable between lots.
- Never pool reagents from different tubes even if they are from the same lot.
- Do not use the reagents after their expiration date.
- Do not interchange caps among reagents as contamination may occur and compromise test results.
- Only open the tubes when adding aliquots into tubes or removing aliquots from tubes. Keep the tubes closed at any other time to avoid contamination.
- To avoid contamination of the environment with amplicons, do not open the reaction tubes post-amplification.
- Avoid microbial and deoxyribonuclease (DNase) contamination of reagents when removing aliquots from tubes. The use of sterile DNase-free disposable filter-blocked or positive displacement pipettor tips is recommended.
- Use a new pipettor tip for each specimen or reagents.
- Additional controls may be tested according to guidelines or requirements of local, state, provincial and/or federal regulations or accrediting organizations.
- For accurate results, pipette carefully using only calibrated equipment. Use of inaccurate volumes may give erroneous results.
- Thoroughly clean and disinfect all surfaces with a 1% bleach solution followed by water.
- Use micropipettes with an aerosol barrier or positive displacement tips for all procedures.
- Testing should be performed in an area with adequate ventilation.
- Dispose of containers and unused contents in accordance with Federal, State and Local regulatory requirements.

- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.
- Wash hands thoroughly after handling.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS) located at quidel.com.

STORAGE AND HANDLING OF KIT REAGENTS

Store the Assay Kit at 2°C to 8°C until the expiration date listed on the outer kit box.

SPECIMEN COLLECTION, STORAGE AND HANDLING

Vaginal/rectal swab specimens from antepartum women for enrichment broth culture should be collected, stored, and handled according to the CDC recommended clinical procedure.

Sample Type: Vaginal/rectal swabs following 18 to 24 hours of incubation at 35° ± 2°C in LIM or Carrot enrichment broth. The cultured enrichment broth can be stored at either 20°C to 25°C for up to 48 hours or 2°C to 8°C for up to 7 days prior to testing.

TEST PROCEDURE

1. Turn on Solana by pressing the power button and wait until it completes self-testing.
   Note: Do not open the lid during the self-testing.
2. Warm the heat block to 95° ± 2°C for 25 minutes prior to the heat lysis step.
3. Place the required number of Process Buffer tubes in the Workflow Tray. Mark the Process Buffer tubes on the cap and/or side of the tube.
   Note: One (1) Process Buffer tube is required for each specimen or control to be tested.
   Note: A maximum of 12 tests can be performed in a single Solana instrument.
4. Vortex the 18- to 24-hour broth culture for 5 seconds and transfer 50 µL of the broth culture to a patient-identified Process Buffer tube.
   Note: The specimens in Process Buffer tubes may be stored at 2°C to 8°C for up to 72-hours.
5. Close the cap and mix the solution well by vortexing the tubes for 5 seconds.
   Note: Use a new pipette tip for each specimen.
6. Heat the Process Buffer tubes at 95° ± 2°C for 5 minutes and then vortex the tubes for 5 seconds.
   Note: Begin 5-minute lysis procedure when the heat block measures 95° ± 2°C. The timer must be stopped if the temperature falls out of range at any time during the 5-minute period and cannot be restarted until the heat block returns to 95° ± 2°C.
   Note: The heated specimens in Process Buffer tubes may be stored at 2°C to 8°C for up to 72-hours.
7. Remove the required number of Reaction Tubes from the protective pouch and place into Transfer Rack. Mark the Reaction Tubes on the cap.
   Note: Remove the excess air and reseal the bag.
8. Transfer 50 µL of the diluted specimen to the labeled Reaction Tube, mix the solution by pipetting up and down vigorously a minimum of 5 times and close the cap. The solution should be clear, free of solid material.
   Note: Use a new pipette tip for each diluted sample.
   Note: Proceed immediately to the next step. Do not allow reconstituted reaction mix to sit for longer than 15 minutes.
9. Enter User ID and Password and press ↵ (ENTER).
10. Select "NEW TEST". If Solana displays a different screen, go to the home screen.
11. Select the tube positions to use.
12. Scan the assay barcode or manually enter Lot ID/Exp Date, select "GBS" assay from the Select Test drop-down menu and press "▶."
13. Enter Sample ID.
14. Select sample type (patient or QC) from the drop-down menu and enter Sample IDs (Optional: see 2nd note in step 16).
15. Using the Solana Transfer Rack to hold Reaction Tubes at eye-level, visually inspect each Reaction Tube to ensure pellet rehydration.
16. Open the lid and place the Reaction Tubes in Solana via the Transfer Rack. Close the lid
    Note: Be sure that all tubes are in tight contact with heat block.

17. Close the lid and press “Start” to initiate the Solana GBS Assay. Solana will display the progress, and the count-down to assay completion. Test results will be displayed on the screen in approximately 30 minutes.
    Note: To avoid laboratory contamination, once the tube has been closed and the amplification reaction started, **DO NOT** open the Reaction Tube.
    Note: While the test is running, sample ID can be entered or edited by pressing the pencil icon.
18. After the run is completed the results can be printed by selecting the print button.

INTERPRETATION OF RESULTS

Samples	Assay Result	Interpretation
Patient specimen	GBS POSITIVE	GBS DNA detected
	GBS NEGATIVE	No GBS DNA detected and PRC detected
	INVALID	No GBS DNA and No PRC detected; for invalid test results, retest the same processed sample first. If the test is invalid upon retesting with the processed sample, re-process another aliquot of the same enrichment broth culture or inoculate a new enrichment culture, incubate for 18 to 24 hours and re-test.

QUALITY CONTROL

The Solana GBS assay incorporates several controls to monitor assay performance.

- The process control is used to monitor sample processing, to detect HDA inhibitory specimens, to confirm the integrity of assay reagents and the operation of the Solana instrument. The process control is included in the Process Buffer tube.
- External positive controls may be treated as a patient specimen. Identify the Process Buffer tube as the positive control and proceed with processing as described above in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure.
- External negative controls may be treated as a patient specimen. Identify the Process Buffer tube as the negative control and proceed with processing as described above in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by GBS DNA or amplicon.

It is recommended that the reactivity of each new lot and each new shipment of the Solana GBS Assay be verified on receipt and before use. External control tests should be performed thereafter in accordance with appropriate federal, state and local guidelines. The Solana GBS assay should not be used in patient testing if the external controls do not produce the correct results.

LIMITATIONS

- The Solana GBS Assay should only be used on the Solana Instrument by trained personnel.
- The Solana GBS Assay does not distinguish between viable and non-viable organisms and should not be used to assess therapeutic success or failure because GBS DNA may persist following antimicrobial treatment.
- The Solana GBS Assay is for use with vaginal/rectal swab specimens collected in accordance with established guidelines for collection of Group B *Streptococcus* culture specimens. Cervical, perianal, perirectal or perineal specimens are not acceptable sample types. A speculum should not be used for sample collection.
- Performance of the Solana GBS Assay was validated with LIM and Carrot broth media only. Performance has not been validated with other GBS selective broth enrichment media.
- The performance of the Solana GBS Assay has been established with LIM and Carrot broth cultures that have been incubated for 18 to 24 hours. The performance of the Solana GBS Assay with cultures incubated <18 hours has not been evaluated.
- The Solana GBS Assay does not provide susceptibility results. Culture isolates are needed for performing susceptibility testing as recommended for penicillin-allergic women.
- GBS colonization during pregnancy can be intermittent, persistent or transient. The clinical utility of GBS screening decreases when testing is performed more than five weeks prior to delivery.
- A negative result does not rule out the possibility of GBS colonization. False negative results may occur when the GBS concentration in the specimen is below the LOD.
- The Solana GBS Assay is not intended to differentiate carriers of GBS from those with streptococcal disease.

- Mutations or polymorphisms in primer or probe binding regions may affect detection of new or unknown variants and may result in a false negative result.
- Results obtained with the Solana GBS Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

EXPECTED VALUES

Clinical performance of the Solana GBS assay with LIM and Carrot enrichment broths was established during a prospective study conducted from July 2017 to September 2017. Seven hundred fifty-three (753) specimens collected from antepartum women between 35 to 37 weeks' gestation at four distinct geographical sites across the United States, were tested. The age range for these women was between 15 to 44 years old. The percentage of positive cases as determined by the Solana GBS assay during the study was 27.7% (208/752).

CLINICAL PERFORMANCE

Seven hundred fifty-three (753) specimens used for this study were collected from antepartum women between 35 to 37 weeks gestation at four distinct geographical sites across the United States. The age range for these women was between 15 to 44 years old. Specimens were inoculated into either LIM or Carrot broth (403 and 350 specimens, respectively) and incubated for 18 to 24 hours at 35°C. Post-incubation specimens were tested by both the Solana GBS Assay and bacterial culture. One (1) specimen (0.2%) was invalid in the Solana GBS Assay when initially tested and upon repeat testing. This specimen has been removed from additional analysis. The table below is for the remaining seven hundred fifty-two (752) specimens.

Sensitivity/Specificity of the Solana GBS Assay for GBS Compared to Bacterial Culture							
Broth Type	N	TP	FP	TN	FN	Sensitivity (95% CI)	Specificity (95% CI)
LIM	402	88	13	301	0	100 (95.8 to 100)	95.9 (93.0 to 97.6)
Carrot	350	97	10	243	0	100 (96.2 to 100)	96.0 (92.9 to 97.8)
Combined	752	185	23*	544	0	100 (98.0 to 100)	95.9 (94.0 to 97.3)

*Nineteen (19) of twenty-three (23) Solana GBS Assay Positive/Bacterial Culture Negative specimens were positive by an additional FDA-cleared molecular test.
Prevalence based on culture = 24.6% (185/752)
Prevalence based on Solana GBS Assay = 27.7% (208/752)

ANALYTICAL PERFORMANCE

Limit of Detection

The analytical sensitivity (limit of detection or LOD) of the Solana GBS assay was determined using genomic GBS DNA and quantified (CFU/mL) cultures of six *Streptococcus agalactiae* strains (ATCC® BAA-611, SS617, SS618, SS619, ATCC 12403, and SS700) serially diluted in a negative LIM Broth enriched vaginal/rectal matrix. The LOD of the Solana GBS assay was furthered confirmed using frozen GBS cells in Negative Carrot Broth matrix.

Target Type				**Determined LOD**		
				Copies/Assay	**CFU/mL**	**CFU/Assay**
GBS Genomic DNA		**Strain Name**	**Serotype**	16.67		
GBS Cells	**Freshly Grown**	ATCC BAA-611	V		$5.9x10^5$	$1.4x10^3$
		SS617	Ia		$8.0x10^5$	$1.9x10^3$
		SS618	Ib		$7.1x10^5$	$1.7x10^3$
		SS619	II		$7.6x10^5$	$1.8x10^3$
		ATCC 12403	III		$2.6x10^6$	$6.3x10^3$
		SS700	Ic		$4.9x10^5$	$1.2x10^3$
	Frozen Cells	ATCC 12403	III		$2.6x10^6$	$6.3x10^3$
	Carrot Broth	ATCC 12403	III		$2.6x10^6$	$6.3x10^3$

The assay LOD for Solana GBS is $2.6x10^6$ CFU/mL and $6.3x10^3$ CFU/assay. The assay LOD does not change when testing frozen cells or in the presence of Carrot broth negative matrix.

Analytical Reactivity (Inclusivity)

The reactivity of the Solana GBS Assay was evaluated against an additional fourteen (14) strains of *Streptococcus agalactiae* with different serotypes or not typed in addition to GBS strains ATCC BAA-611, SS617, SS618, SS619, ATCC 12403, and SS700 used in the LOD study. The testing was performed at 1x LOD ($2.6x10^6$ CFU/mL) level of the assay. All additional fourteen (14) strains were detected in the Solana GBS Assay. The serotypes of these GBS strains are listed in the table below:

GBS Strains at 1x LOD ($2.6x10^6$ CFU/mL)	
GBS Strain	**Serotype**
ATCC 12973	II
CCUG 28551	IV
CCUG 29785	VI
CNCTC 6609	VII
BAA-2669	VIII
BAA-2668	IX
ATCC 49449	X
ATCC 27956	Not typed
ATCC 7077	Not typed
ATCC 4768	Not typed
ATCC 12927	Not typed
ATCC 9925	Not typed
ATCC 55194	Not typed
ATCC 55191	Not typed

Analytical Specificity – Cross-reactivity and Microbial Interference

A study was performed to determine if ninety-seven (97) microorganisms or viruses (eighty-two (82) bacteria, three (3) yeast, eleven (11) viruses and a parasite (1)) potentially found in vaginal/rectal samples cross-react with the Solana GBS Assay. The same ninety-seven (97) microorganisms were used to determine if they interfered with one GBS strain (ATCC 12403) at 2x LOD ($5.2x10^6$ CFU/mL) in the Solana GBS Assay The microorganisms were tested above clinically relevant levels (bacteria ≥ $1x10^6$ CFU/mL, viruses the ≥ $1x10^5 TCID_{50}$/mL).

Human genomic DNA was also evaluated for cross-reactivity and interference.

Bacteria		
Aeromonas hydrophila (2 strains)	*Enterococcus faecalis*	*Salmonella enterica enterica Serovar Typhimurium*
Abiotrophia defective	*Enterococcus faecium*	*Salmonella enterica indica*
Acinetobacter baumanii	*Escherischia coli*	*Serratia liquefaciens*
Alcaligenes faecalis faecalis	*Escherischia fergusonii*	*Serratia marcescens*
Bacillus cereus	*Gardnerella vaginalis*	*Shigella boydii*
Bacillus subtilis (2 strains)	Group C Strep	*Shigella flexneri*
Bacteroides fragilis (2 strains)	*Helicobacter pylori*	*Shigella sonnei*
Bifidobacterium adolescentis (2 strains)	*Klebsiella oxytoca*	*Staphyloccocus aureus*
Campylobacter fetus	*Klebsiella pneumoniae*	*Staphylococcus epidermidis*
Campylobacter hyointestinalis	*Lactobacillus acidophilus*	*Stenotrophomonas maltophila*
Campylobacter jejuni (2 strains)	*Legionella pneumophila*	*Streptoccocus mutans*
*Chlamydia trachomatis**	*Listeria monocytogenes*	*Streptoccocus pyogenes*
Citrobacter freundii	*Mobiluncus mulieris*	*Streptococcus bovis*
Clostridium bifermentans	*Moraxella cartarrhalis*	*Streptococcus dysgalactiae*
Clostridium butyricum	*Morganella morganii*	*Streptococcus gordonii*
Clostridium difficile	*Neisseria gonorrhoeae*	*Streptococcus intermedius*
Clostridium haemolyticum	*Peptostreptococcus anaerobius*	*Streptococcus mitis*
Clostridium novyi	*Pleisiomonas shigelloides*	*Streptococcus oralis*
Clostridium orbiscindens	*Porphyromonas asaccharolytica*	*Streptococcus pneumoniae*
Clostridium perfringens	*Prevotella melaninogenica*	*Streptococcus salivarius*
Clostridium septicum	*Proteus mirabilus*	*Streptococcus suis*
Clostridium sordellii	*Providencia alcalifaciens*	*Streptococcus uberis*
Clostridium sporogenes	*Pseudomonas aeruginosa*	*Ureaplasma urealyticum*
Edwardsiella tarda	*Pseudomonas fluorescens*	*Vibrio parahaemolyticus*
Enterobacter aerogenes	*Salmonella choleraesius (typhimurium)*	*Yersinia enterocolitica*
Enterobacter cloacae	*Salmonella enterica arizonae*	

* Tested at 10^6 Inclusion Forming Units/mL

Yeast		
Candida albicans	*Candida glabrata*	*Candida parapsilosis*

Viruses		
Adenovirus	Enterovirus	Norovirus
CMV	HPV-16†	Rotavirus
Coxsackie virus	HSV1 (Macintyre)	VZV
Echovirus	HSV2 (G)	

† Tested using a transformed cell line at 1 x 10^5copies/mL

Parasite
Trichomonas vaginalis§

§ Tested at 10^6 trichomonads/mL

None of the organisms or viruses tested above cross-reacted or interfered with the performance of the Solana GBS Assay.

Human genomic DNA did not cross-react or interfere with the performance of the Solana GBS Assay.

Analytical Specificity – Interfering Substances

The performance of Solana GBS Assay was evaluated with thirty-four (34) potentially interfering substances that may be present in vaginal/rectal specimens. The substances were tested with GBS negative matrix in the presence or absence of GBS cells (strain ATCC 12403) at 2x LOD ($5.2x10^6$ CFU/mL) in the Solana GBS Assay.

Substance Name	Test Concentration in Contrived Sample	Substance Name	Test Concentration in Contrived Sample
Cortizone 10 (Hydrocortisone)	0.1% Swab Amount/µL	Hemoglobin	64 µg/mL
Desitin (Zinc Oxide)	0.1% Swab Amount/µL	Prilosec (Esomeprazole Magnesium Hydrate)	10 µg/mL
Urine	2% (v/v)	Fecal Fat- Stearic Acid	520 µg/mL
Preparation H (Phenylephrine)	0.04% (w/v)	Tagamet (Cimetidine)	10 µg/mL
Tums (Calcium Carbonate)	10 µg/mL	Miconazole Nitrate Salt	0.04% (w/v)
Mylanta (AI(OH)3, MG(OH)3)	2 µg/ml	Nystatin	200 USP U/ml
Fleet Mineral Oil Enema	0.2% (v/v)	Fecal Sugar- Dextrose	20 µg/mL
Gynol II Vaginal Contraceptive (Nonoxynol-9)	0.1% Swab Amount/µL	Human Serum Albumin	200 µg/mL
Imodium AD (Loperamide HCl)	20 µg/ml	Triclosan	0.002% (w/v)
Pepto Bismol (Bismuth subsalicylate)	17 µg/ml	Hemorrhoidal cream (Target Brand Cream)	0.1% Swab Amount/µL
Tucks personal cleaning pads (Witch hazel)	2% (v/v)	KY Jelly	0.1% Swab Amount/µL
Benzalkonium Chloride Towelettes	0.0024% (v/v)	Petroleum Jelly	0.1% Swab Amount/µL
Ethanol	0.2% (v/v)	Body Powder	0.1% Swab Amount/µL
Whole Blood	2% (v/v)	Meconium	0.1% Swab Amount/µL
Fecal Fat- Palmitic acid	26 µg/ml	Baby Powder	0.1% Swab Amount/µL
Mucin	60 µg/mL	Amniotic Fluid	2% (v/v)
Barium Sulfate	100 µg/mL	Stool	0.1% Swab Amount/µL

Reproducibility Study

A four-sample panel consisting of three (3) levels of contrived positive samples and a negative contrived sample were tested in this study. *Streptococcus agalactiae* strains SS617 or SS618 were diluted in negative matrix to 3x LOD ($2.4x10^6$ CFU/mL and $2.1x10^6$ CFU/mL respectively) for moderate positive, 1x LOD ($8.0x10^5$ CFU/mL and $7.1x10^5$ CFU/mL respectively) for low positive and diluted to C20 to C80 for high negative / low positive ($8.0x10^3$ CFU/mL and $7.1x10^3$ CFU/mL respectively). Negative matrix without spiked organism was used for the negative sample. The Solana GBS Assay was used per the instructions for use.

Panels and controls were tested at each site by two (2) operators per instrument for five (5) days, each sample tested in three (3) replicates, for a total of 90 results per level (2 operators x 5 days x 3 sites x 3 replicates).

Reproducibility Summary

Reproducibility Samples	SITE						Overall Percent Agreement		95% Confidence Interval
	Site #1		Site #2		Site #3				
	# Expected Result/# tested	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*			
GBS strain SS617 High Negative‡ ($8.0x10^3$ CFU/mL)	11/16	68.8	9/16	56.3	8/16	50.0	28/48	58.3	44.3 to 71.2
GBS strain SS617 Low Positive ($8.0x10^5$ CFU/mL)	16/16	100	16/16	100	16/16	100	48/48	100	92.6 to 100
GBS strain SS617 Moderate Positive ($2.4x10^6$ CFU/mL)	16/16	100	16/16	100	16/16	100	48/48	100	92.6 to 100
GBS strain SS618 High Negative ($7.1x10^3$ CFU/mL)	2/14	14.3	6/14	42.9	4/14	28.6	12/42	28.6	17.2 to 43.6

Reproducibility Summary									
Reproducibility Samples	SITE						Overall Percent Agreement		95% Confidence Interval
	Site #1		Site #2		Site #3				
	# Expected Result/# tested	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*	*# Expected Result/# tested*	*% Agreement with Expected Result*			
GBS strain SS618 Low Positive ($7.1x10^5$ CFU/mL)	14/14	100	14/14	100	14/14	100	42/42	100	91.6 to 100
GBS strain SS617 Moderate Positive ($2.1x10^6$ CFU/mL)	14/14	100	14/14	100	14/14	100	42/42	100	91.6 to 100
Negative Sample	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100
GBS Positive Control	30/30	100	30/30	100	30/30	100	90/90	100	95.9 to 100
GBS Negative Control	0/30	100	0/30	100	0/30	100	0/90	100	95.9 to 100

‡ The Expected Result for High Negative samples was Negative

Carryover – Cross Contamination

A study was conducted to demonstrate that carry-over and cross contamination does not occur when the intended users perform the Solana GBS Assay following PI instructions.

Two (2) samples were prepared: GBS positive sample and GBS negative sample. The positive sample was prepared by adding cells of one GBS strain with a known titer to negative LIM broth matrix at the concentration of $1.8x10^8$ CFU/mL. The negative LIM broth matrix served as the GBS negative sample. In each experiment, the positive samples were alternated with the negative samples and tested using Solana GBS Assay to assess the risk of cross contamination. In total, two (2) operators tested a total of 50 positive and 50 negative samples over a total of 11 runs.

All positive GBS samples were positive and all negative samples were negative. No evidence of carry-over/cross contamination was observed with the Solana GBS Assay when performed in accordance with the package insert.

CUSTOMER AND TECHNICAL SUPPORT

If you have any questions regarding the use of this product, please contact Quidel Technical Support at 1.800.874.1517 (in the U.S.) or technicalsupport@quidel.com. If outside the U.S., further information can be obtained from your distributor, or directly from Quidel at one of the numbers listed below. Reference **quidel.com** to see more options for Support.

Country	Phone	E-Mail Address
Europe, Middle East and Africa	+353 (91) 412 474 (main) 0 1800 200441 (toll free)	emeatechnicalsupport@quidel.com
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France	0 (805) 371674	
Germany	+49 (0) 7154 1593912	
Netherlands	0 800 0224198	
Switzerland	0 800 554864	
United Kingdom	0 800 3688248	
Italy	+39 (800) 620 549	
North America, Asia-Pacific, Latin America	858.552.1100	technicalsupport@quidel.com
Canada	437.266.1704 (main) 888.415.8764 (toll free)	technicalsupport@quidel.com
China	0400 920 9366 or +86 021 3217 8300	chinatechnicalservice@quidel.com

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REFERENCES

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M311 – Solana GBS Assay – 48-Test Kit

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Revision Changes:

- Add Intellectual Property section.

GLOSSARY

REF Catalogue number	CE CE mark of conformity
EC REP Authorized Representative in the European Community	LOT Batch code
 Use by	 Manufacturer
 Temperature limitation	 Intended use
Rx ONLY Prescription use only	 Consult e-labeling instructions for use
IVD For *In Vitro* diagnostic use	 Contains sufficient for 48 determinations
CONT Contents/Contains	